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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,669	07/12/2000	Bruce Ernest Tepper	8168	2159

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	PAPER NUMBER
1644	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
64,669	TEPPER et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 10/17/01 & 1/9/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims 5-11

☑ Claim(s) 1-6-11, 13-20 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) 5-11 is/are allowed.

☑ Claim(s) 1-6-11, 13-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Applicant's responses of 10/17/01 and 1/9/02 (Papers 7 and 9) have been entered. Claims 1, 4-11 and 13-20 are pending and under examination.

Applicant's election with traverse of the species combination of a chemical primary challenge and a physical secondary challenge in Paper No. 7 is acknowledged. The traversal is on the ground(s) that no reason has been given for the distinctness of the species and the examiner and has not demonstrated a serious search burden. This is not found persuasive because the office sees these as distinct because a reference showing one embodiment (e.g. a physical primary challenge, such as UV light) and a chemical secondary challenge, such as acetone) would not fairly teach or suggest an embodiment of a chemical primary challenge (e.g. artificial stool) and a physical secondary challenge (e.g. tape stripping). Further the latter of these embodiments, would not even fairly suggest an embodiment of a chemical primary challenge (artificial stool) and a chemical secondary challenge (e.g. acetone). The different embodiments set forth in the election of species requirement are these properly considered patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Additionally, with respect to the restriction the Office considers that there would be a serious search burden in examining all of the combinations of species of the primary and secondary challenges, since as noted supra a reference teaching one embodied combination of primary and secondary challenges would not necessarily teach any of the others. Examination would therefore require the citing of multiple disparate references. Furthermore, the class/subclasses that would be required for the different embodiments --e.g. The instantly

claimed embodiment requires a search in class/subclasses 424/9.8-9.81 and 600/556, while other embodiments would require a search in class/subclasses 600/310,382 and 552-555.

Claims 8 and 9 are objected to under 37 CFR 1.75(I) because they fail to commence the recitation of each recited element with an indentation. Note claim 8, part a) has two "applying" steps. Claim 9 as three "assessing" steps and a "drawing" step.

1, 5-11 and 13-20

Claims ~~1-20~~ are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

DKS 6/24/03

Claim 1 is unclear as to what the claimed method does, since there is no purpose stated in the preamble. That is no clear conclusion or resolution is drawn from the assessment of step C).

Claims 1 and 8 are each recite a "test site"; however, it is not clear what is being tested -- e.g. the capacity of the "responsive system" to respond (e.g. testing whether an animal can mount an immune response to a known antigen), or the ability of the primary and/or secondary challenge(s) to induce a response in the "responsive system" (e.g. to determine if a given substance is immunogenic in an immunocompetent animal).

Claims 1 and 9 are unclear by reciting "assessing" the response, because it is unclear how or where the response is assessed. Is the response assessed by observing a response at the test site? Is the response assessed by observing the state of the whole responsive system (e.g. anaphylactic shock in an animal following injection of an antigen at a test site).

To overcome applicant may more tightly define claim terms as set forth at specification pages 3-4 and 8.

In claims 5-6, 10-11 it is not clear whether "pre-challenge", "concurrent-challenge" and "post-challenge" are each referring to the primary or to the secondary challenge.

Claim 8 is unclear as to what the "study" does, since there is no purpose stated in the claim preamable. Claim 8 is unclear as to what the "study" is and what the result of the "study" is. For example, two challenges are applied, but no result of these challenges is observed, assessed, or measured.

In step b) it is not clear what the "controls" may be. Are they "control" substances applied as the primary (chemical) challenge, or are they are "control" subjects (e.g. individuals known to have or not have a given disease), or are they "control" test sites on the same organism that has experimental test sites?

The relationship between steps a) and b) is unclear.

It is not clear if the "controls" of step b) are merely to be identified form among the members of the responsive system that were challenged in parallel with the subjects challenged in step a)). If the latter is intended, it is to be noted that the claim is devoid of any positive step that does anything to the controls, and is devoid of any step that compares any results observed for the subjects and the controls.

Claim 9 depending from 8, states little that would clarify claim 8. It does not positively state who or what the "controls" are, whether they are control subjects or control substance, or

what is to be done with the controls (e.g. challenged if they are subjects, or administered as a challenge if they are substances) other than that they are subjected to an "assessing".

The last step of claim 9 of "drawing conclusions" is indefinite because the claim fails to positively state what is done with the various "assessments". Are the "assessments" of challenges obtained from members of the "responsive system" to be compared with "assessments" of whatever it is that has done to or with the "controls"?

It is suggested that applicant address the rejections pertaining to claims 8-9 by reciting one independent claim that incorporates all elements of claims 8 and 9 in a clear manner stating how the "study" leads to some kind of result.

Claims 16-20 are unclear as to how the patch of claim 15 would be applied to the cell cultures of claim 16.

In claim 19, "A" is indefinite. The claim must be amended to recite --The--.

In claim 20 "The clinical study" lacks antecedent basis.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Dwj 1/24/03

Claims ~~1-20~~ 1, 5-11 and 13-20 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. As noted supra in the 112, second paragraph rejection, claims 1 and 8 fail to recite any useful result of the method or study, in that nothing is observed, assessed, or measured; and/or nothing is positively concluded from the method.

Merely applying "challenges" to a responsive system, without observing/assessing/measuring some result(s) thereof and drawing some kind of conclusion from

such results fails to constitute a "study" that is of any utility, since such mere "applying" results in nothing that anyone can use.

Applicant may address this utility rejection by amending the claims as suggested supra with respect to the 112 second paragraph rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 7-9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Kapadia et al. (5,935,581).

Kapadia et al. show a test/study method in which the skin of mice serves as a "responsive system". The "response" in these tests is the formation of papillomas/epidermal tumors. Applicant is referred to. Figs. 1 and 4; col. 3, lines 43-64; col. 7, lines 32-38; and col. 24; lines 32-48.

More specifically these portions of the disclosure show, at stage 1, the application of the known tumor initiator DMBA to a site on the skin. This step corresponds to the instant step of "subjecting the test site of a responsive system to a primary challenge."

One week after application of the initiator, at stage 2, the mice are treated with ultraviolet B radiation (twice a week for twenty weeks), which serves as a tumor promoter. This step

corresponds to the instant step of "subjecting the test site to a secondary challenge". This correspondence is clearly correct since the radiation enhances tumor formation initiated by the DMBA.

Throughout and after the 20 weeks, the mice are assessed for the appearance of papillomas/epidermal tumors. This step corresponds to the instant step of "assessing the response".

Claim 1 is thus clearly anticipated.

The mice of Kapadia et al. receive a test compound during the time course of irradiation. This compound is administered via the drinking water or via topical application to the skin. This test compound (e.g. a food colorant) is evaluated for its ability to inhibit tumor formation. Control mice (right hand side of Fig. 1) receive no such test compound and typically develope papillomas/epidermal tumors. These mice may thus be considered as "negative controls", if such are interpreted to mean subjects receiving no test compound. Alternatively such mice may be considered as "positive controls"; of such are interpreted to mean subjects that show a positive response to the challenge(s), in this case tumor formation. Accordingly the "controls" of claim 8 are anticipated, and the "interventions" of claim 11 are anticipated. Claim 9 is clearly anticipated since the response is assessed throughout the 20 weeks of radiation treatment.

Applicant's claims are so vague and broad that the statement of anticipation is proper.

Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Fruehauf et al. (6,008,007).

Fruehauf et al. show a method of assessing for the synergistic effects radio-sensitizing/chemotherapeutic drugs and radiation treatments upon isolated cancer cells in wells of a tissue culture plate. The sensitizing/chemotherapeutic agent and the radiation can be administered concurrently or sequentially. The effects of these treatments upon cell proliferation are assessed by measuring the incorporation of tritiated thymidine. Applicant is referred especially to col. 4, lines 10-22 and 50-62; col. 5; lines 3-55; col. 6, lines 28-49; col. 7, lines 19-47; col. 9, line 33 - col. 10, line 23; and claim 7.

In these assays of Fruehauf et al., the sensitizing/chemotherapeutic drug corresponds to the instant primary challenge, the radiation corresponds to the instant secondary challenge, and the culture well corresponds to the instant test site. Fruehauf et al. employ wells that serve as positive and negative controls. See col. 6, lines 34-38 and 64-67; col. 9, lines 49-54. Thus the "controls" of instant claim 8 are anticipated.

The claims are sufficiently vague and broad that they are properly anticipated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

D. Saunders:jmr

March 19, 2002